Updated: 03/2019
PARP Approved: 03/2019

Gateway Health
Prior Authorization Criteria
Granulocyte Colony Stimulating Factors

All requests for Granulocyte Colony Stimulating Factors require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Granulocyte Colony Stimulating Factors Prior Authorization Criteria:
The following G-CSFs are formulary:

- **Neupogen (filgrastim)**
- **Granix (tbo-filgrastim)**

All other G-CSFs are considered non-formulary and require documentation of failure with one of the formulary G-CSFs with a shared indication in addition to meeting the criteria outlined below:

- **Neulasta (pegfilgrastim)**
- **Fulphila (pegfilgrastim-jmdb)**
- **Zarxio (filgrastim-sndz)**
- **Nivestym (filgrastim-aafi)**
- **Leukine (sargramostim)**
- **Udenyca (pegfilgrastim-cbqv)**

For all requests for Granulocyte Colony Stimulating Factors all of the following criteria must be met:

- All requests must be prescribed by, or in consultation with, an oncologist or hematologist
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines

Coverage may be provided with a diagnosis of primary prophylaxis of febrile neutropenia (FN) and the following criteria are met:

- Request must be for Neupogen (filgrastim), Nivestym (filgrastim-aafi), Zarxio (filgrastim-sndz), Neulasta (pegfilgrastim), Fulphila (pegfilgrastim-jmdb), Udenyca (pegfilgrastim-cbqv), or Granix (tbo-filgrastim)
- Must also meet ***at least one*** of the following:
    - Must have a solid tumor or non-myeloid malignancy and be receiving myelosuppressive chemotherapy which has a greater than 20% risk of FN, as indicated in current American Society of Clinical Oncology and National Comprehensive Cancer Network guidelines for myeloid growth factors
    - Must have a solid tumor or non-myeloid malignancy and be receiving nonmyelosuppressive chemotherapy which has 10-20% risk of FN, and be considered to be at high risk for chemotherapy-induced FN or infection due to ***at least one*** of the following:
        - Age greater than 65 years
        - Poor performance status
        - Previous episode of FN
        - Extensive prior treatment including large radiation ports

        - Previous chemotherapy or radiation therapy
        - Preexisting neutropenia
        - Cytopenias due to bone marrow involvement by tumor
        - Poor nutritional status
        - Presence of open wounds or active infections
        - Recent surgery
        - Advanced cancer
        - Cardiovascular disease
        - Mucositis
        - Poor renal function
        - Liver dysfunction, most notably elevated bilirubin
    - Must be receiving a dose-dense chemotherapy regimen for the treatment of node-positive breast cancer, small-cell lung cancer, or diffuse aggressive non-Hodgkin's Lymphoma

Coverage may be provided with a diagnosis of secondary prophylaxis of febrile neutropenia and the following criteria are met:

- Request must be for Neupogen (filgrastim), Nivestym (filgrastim-aafi), Zarxio (filgrastim-sndz), Neulasta (pegfilgrastim), or Granix (tbo-filgrastim)
- Member must have a documented episode of neutropenia from a prior cycle of chemotherapy for which primary prophylaxis was not received and a reduction in dose may compromise treatment outcome.

Coverage may be provided for the mobilization of progenitor cells into peripheral blood for collection by leukophoresis and the following criteria is met:

- Request must be for Neupogen (filgrastim), Leukine (sargramostim), Nivestym (filgrastim-aafi), or Zarxio (filgrastim-sndz)

Coverage may be provided to reduce the duration of severe neutropenia following autologous stem-cell transplantation and the following criteria is met:

- Request must be for Neupogen (filgrastim), Nivestym (filgrastim-aafi), or Zarxio (filgrastim-sndz)

Coverage may be provided to reduce time to neutrophil recovery and duration of fever in adult patients with acute myeloid leukemia receiving induction or consolidation therapy and the following criteria is met:

- Request must be for Neupogen (filgrastim), Nivestym (filgrastim-aafi), or Zarxio (filgrastim-sndz)

Coverage may be provided with a diagnosis of congenital, cyclic, or idiopathic neutropenia and the following criteria are met:

- Request must be for Neupogen (filgrastim), Nivestym (filgrastim-aafi), or Zarxio (filgrastim-sndz)
- Must have experienced an infection requiring antibiotic treatment during the previous 12 months

- For congenital or idiopathic neutropenia must have at least three documented episodes of severe chronic neutropenia (ANC <500/uL) during a 6 month period
- For cyclic neutropenia must have documentation of 5 consecutive days of severe neutropenia (ANC <500/uL) per cycle

Coverage may be provided to increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome) and the following criteria is met:

- Request must be for Leukine (sargramostim), Neupogen (filgrastim) or Neulasta (pegfilgrastim)

Coverage may be provided to shorten time to neutrophil recovery and to reduce the incidence of severe, life-threatening, or fatal infection in patients 55 years or older with acute myelogenous leukemia and the following criteria is met:

- Request must be for Leukine (sargramostim)

Coverage may be provided for myeloid recovery following bone marrow transplant and the following criteria are met:

- Request must be for Leukine (sargramostim)
- Must meet one of the following criteria:
    - Must have undergone allogenic bone marrow transplant from HLA-matched related donor
    - Must have undergone autologous bone marrow transplant for non-Hodgkin's lymphoma, acute lymphoblastic leukemia, or Hodgkin's disease
    - Must have failed or delayed engraftment post bone marrow transplant as defined below:
        - Delay in engraftment: ANC ≤ 100 cells/mm3 by day 28 posttransplantation **OR** ANC ≤ 100 cells/mm3 by day 21 posttransplantation with evidence of active infection
        - Engraftment failure: average of ANC ≥ 500 cells/mm3 for at least one week followed by loss of engraftment with ANC < 500 cells/mm3 for at least one week beyond day 21 posttransplantation

Initial Duration of Approval: 3 months
Reauthorization criteria

- Must continue to meet criteria for medical necessity as outlined above

Reauthorization Duration of approval: 3 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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Granulocyte Colony Stimulating Factors (G-CSFs)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Physician:	NPI:
Physician Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Patient Name:	DOB:
Gateway ID:	Weight (kg): Date:

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the patient currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY

Diagnosis: _____

For primary prophylaxis of febrile neutropenia (FN) only:

Is the member receiving a dose-dense chemotherapy regimen for the treatment of node-positive breast cancer, small-cell lung cancer, or diffuse aggressive non-Hodgkin's Lymphoma? ☐ Yes ☐ No

Does the patient have a solid tumor or non-myeloid malignancy? ☐ Yes ☐ No

Please indicate the member's percent (%) risk of FN per current American Society of Clinical Oncology and National Comprehensive Cancer Network guidelines: _____

Please check any applicable FN risk factors:

☐ Member has poor performance status
☐ Member has preexisting neutropenia
☐ Member has had a previous episode of FN
☐ Member has had a recent surgery
☐ Member has extensive prior treatment including large radiation ports
☐ Member has had previous chemotherapy or radiation therapy
☐ Member has cytopenias due to bone marrow involvement by tumor
☐ Member has poor nutritional status
☐ Member has advanced cancer
☐ Member has open wounds or active infections
☐ Member has mucositis
☐ Member has cardiovascular disease
☐ Member has poor renal function
☐ Member has liver dysfunction, most notably elevated bilirubin

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MEMBER INFORMATION	
Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

MEDICAL HISTORY (Continued)

For secondary prophylaxis of febrile neutropenia (FN) only:

Has the member had an episode of neutropenia from a prior cycle of chemotherapy for which primary prophylaxis was not received? ☐ Yes ☐ No

Would a reduction in chemotherapy dose compromise treatment outcome? ☐ Yes ☐ No

For congenital or idiopathic neutropenia only:

Has the member experienced an infection requiring antibiotic treatment in the past 12 months? ☐ Yes ☐ No

Does the member have at least three documented episodes of severe chronic neutropenia (ANC <500/ul) during a 6 month period? ☐ Yes ☐ No (If yes, please provide documentation)

For cyclic neutropenia only:

Has the member experienced an infection requiring antibiotic treatment in the past 12 months? ☐ Yes ☐ No

Does the member have at least five consecutive days of severe neutropenia (ANC <500/ul) per cycle? ☐ Yes ☐ No

(If yes, please provide documentation)

For myeloid recovery following bone marrow transplant only:

Has the member undergone allogenic bone marrow transplant from HLA-matched related donor? ☐ Yes ☐ No

Has the member undergone autologous bone marrow transplant for non-Hodgkin's lymphoma, acute lymphoblastic leukemia, or Hodgkin's disease? ☐ Yes ☐ No

Please check any applicable boxes (documentation also required):

☐ Member has or had ANC ≤ 100 cells/mm3 by day 28 posttransplantation

☐ Member has or had ANC ≤ 100 cells/mm3 by day 21 posttransplantation with evidence of active infection

☐ Member has or had an average of ANC ≥ 500 cells/mm3 for at least one week followed by loss of engraftment with ANC < 500 cells/mm3 for at least one week beyond day 21 posttransplantation

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Physician Signature	Date